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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,980	10/26/2005	Martin Alan Lee	41577/314737	9249

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EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT	PAPER NUMBER
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1637

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09/02/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/530,980	Applicant(s) LEE ET AL.	
	Examiner Suryaprabha Chunduru	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 43,46-69,87 and 88 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 43,46-69,87 and 88 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants are herein informed regarding the change of examiner of this case.
2. The Applicants' response to the office action field on June 18, 2009 has been considered and acknowledged.

Status of the application

3. Currently claims 43, 46, 48-69, 87-88 are pending under examination. Claims 1-42, 44-45, 47, 70-86 are cancelled. Applicants' arguments and the amendment have been fully considered and deemed persuasive for the reasons that follow. The rejections that are not reiterated herein are withdrawn.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 43, 48-53, 57-69 are rejected under 35 U.S.C. 102(b) as being anticipated by Higuchi (EP 0 872562 A1).

Higuchi teaches a method of claims 43, 48-53, 57-68, for detecting the presence of a target nucleic acid sequence in a sample comprising

(a) adding to a sample suspected of containing the target nucleic acid sequence, a fluorescently labeled probe specific for the target nucleic sequence, and a DNA duplex binding

agent which can absorb fluorescent energy from the fluorescent label on the probe, wherein the duplex DNA binding agent is daunomycin (see page 8, line 29-37, page 5, line 24-33);

(b) subjecting the mixture to an amplification reaction (see page 5, line 24-33);

(c) subjecting the sample under conditions which the probe hybridizes to the target nucleic acid (see page 5, line 24-33);

(d) monitoring fluorescence from the fluorescent label on the probe, wherein the probe is released intact from the target nucleic acid (see page 5, line 24-33, page 10, line 17-26).

With regard to claim 61, Higuchi teaches use of thermostable polymerase (see page 6, line 1-4).

With regard to claims 62-64, 67-68, Higuchi teaches that reaction conditions are characterized by temperature conditions (see page 5, line 50-56).

With regard to claims 65, 69, Higuchi teaches that the method is used to detect polymorphisms (see page 10, line 27-31). Accordingly the claims are anticipated.

Nonstatutory Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 43, 46, 48-69, 87-88 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of US patent 6,833,257('257) in view of Higuchi (EP 0 872562 A1).

Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 of the patent '257 is drawn to a method for detecting a target nucleic acid sequence comprising adding to a sample suspected of containing said target nucleic acid, a DNA duplex binding agent, and a fluorescently labeled probe, subjecting the mixture to an amplification and hybridization conditions and monitoring the fluorescence from the sample after hybridization of the probe and the dissociation of the probe from the target nucleic acid. Further the dependent claims 2-16 further define the method. The instant claims 43-70, 85-86 are within the scope of the patented claims and encompass said method steps. The only obvious variation in the instant claims to that of the patented claims is DNA binding agent as a mitoxantrone or a salt of mitoxantrone and daunomycin.

Higuchi teaches a method for detecting the presence of a target nucleic acid sequence in a sample comprising

(a) adding to a sample suspected of containing the target nucleic acid sequence, a fluorescently labeled probe specific for the target nucleic sequence, and a DNA duplex binding agent which can absorb fluorescent energy from the fluorescent label on the probe, wherein the duplex DNA binding agent is daunomycin (see page 8, line 29-37, page 5, line 24-33); (b) subjecting the mixture to an amplification reaction (see page 5, line 24-33); (c) subjecting the sample under conditions which the probe hybridizes to the target nucleic acid (see page 5, line

24-33);(d) monitoring fluorescence from the fluorescent label on the probe, wherein the probe is released intact from the target nucleic acid (see page 5, line 24-33).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the method as taught by ('257) patented claims with use of daunomycin as DNA binding agents as taught by Higuchi et al. to achieve the expected advantage of developing an improved and sensitivity method for detecting the target nucleic acid sequence. One of the ordinary skill in the art would have been motivated to combine the method of ('257) patented claims with daunomycin as DNA binding agents as taught by Higuchi et al. because one skilled in the art would have a reasonable expectation of success that the combination would result in reducing the non-specific background in detecting a target nucleic acid because Dower et al. explicitly taught that the daunomycin as DNA binding agents are useful in producing distinguishable signals when bound or unbound to double-stranded DNA and single-stranded DNA and aid in homogenous detection method (see page 4, line 44-58, page 5, line 24-33) and such a modification of the art is considered obvious over the cited prior art.

Response to Arguments:

6. With regard to the objection to the claim 71, Applicants' arguments and the amendment were fully considered and found persuasive. The objection is withdrawn herein in view of the amendment.

7. With regard to the rejection of claims 43-70, 85-86 under USC 112 first paragraph (written description and enablement), Applicants' arguments and the amendment were fully considered and found persuasive and the rejection is withdrawn in view of the amendment.

8. With regard to the rejection of claims 43-70, 85-86 under USC 112 second paragraph, Applicants' arguments and the amendment were fully considered and found persuasive and the rejection is withdrawn in view of the amendment.
9. With regard to the rejection of claims 43-45, 47-55, 59-70, 85-86 under USC 102 (b) as being anticipated by Fisher, Applicants' arguments and the amendment were fully considered and found persuasive and the rejection is withdrawn in view of the amendment.
10. With regard to the rejection of claims 43-44, 48-69 under USC 102 (b) as being anticipated by Lee, Applicants' arguments and the amendment were fully considered and found persuasive and the rejection is withdrawn in view of the amendment.
11. With regard to the rejection of claim 46 under USC 103 (a) as being unpatentable over Fisher in view of Smith, Applicants' arguments and the amendment were fully considered and found persuasive and the rejection is withdrawn in view of the persuasive arguments regarding the DNA binding agent.
12. With regard to the rejection of claims 45-47, 70, 85-86 under USC 103 (a) as being unpatentable over Lee in view of Smith, Applicants' arguments and the amendment were fully considered and found persuasive and the rejection is withdrawn in view of the persuasive arguments regarding the DNA binding agent.
13. With regard to the rejection of claims 56-58 under USC 103 (a) as being unpatentable over Fisher in view of Lee , Applicants' arguments and the amendment were fully considered and found persuasive and the rejection is withdrawn in view of the persuasive arguments regarding the DNA binding agent.

14. With regard to the rejection of claims 43-70, 85-86 under nonstatutory obviousness double patenting over US 6,833,257 in view of Smith, Applicants' arguments and the amendment were fully considered and found persuasive and the rejection is withdrawn in view of the persuasive arguments regarding the DNA binding agent.

Conclusion

Claims 46, 54-56, and 87-88 are free of art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Suryaprabha Chunduru/

Primary Examiner, Art Unit 1637

Application/Control Number: 10/530,980
Art Unit: 1637

Page 8